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EXAMINER	
ART UNIT	PAPER NUMBER
	7

DATE MAILED: 03/03/97

NOTICE OF ABANDONMENT

This application is abandoned in view of:

1. ☑ Applicant's failure to respond to the Office letter, mailed 7/19/96.
2. ☐ Applicant's letter of express abandonment which is in compliance with 37 C.F.R. 1.138.
3. ☑ Applicant's failure to timely file the response received _____ within the period set in the Office letter.
4. ☐ Applicant's failure to pay the required issue fee within the statutory period of 3 months from the mailing date of _____ of the Notice of Allowance.
   - ☐ The issue fee was received on _____.
   - ☐ The issue fee has not been received in Allowed Files Branch as of _____.

   In accordance with 35 U.S.C. 151, and under the provisions of 37 C.F.R. 1.316(b), applicant(s) may petition the Commissioner to accept the delayed payment of the issue fee if the delay in payment was unavoidable. The petition must be accompanied by the issue fee, unless it has been previously submitted, in the amount specified by 37 C.F.R. 1.17(l), and a verified showing as to the causes of the delay.

   If applicant(s) never received the Notice of Allowance, a petition for a new Notice of Allowance and withdrawal of the holding of abandonment may be appropriate in view of Delgar Inc. v. Schuyler, 172 U.S.P.Q. 513.
5. ☐ Applicant's failure to timely correct the drawings and/or submit new or substitute formal drawings by _____ as required in the last Office action.
   - ☐ The corrected and/or substitute drawings were received on _____.
6. ☐ The reason(s) below.

Jasemine C. Chambers

JASEMINE C. CHAMBERS, PHD.
SUPERVISORY PATENT EXAMINER
GROUP 1800

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 and 17, drawn to a DNA sequence encoding a *patched* protein, an expression cassette, a cell comprising the cassette and a method for producing *patched* protein by growing the cell, classified in Classes 536 and 435, subclasses 23.1 and 69.1, respectively, for example.

II. Claims 13-16, drawn to a cell comprising an expression cassette comprising a *patched* gene promoter and a heterologous/marker gene and a method of using the same for following embryonic development, classified in Class 435, subclasses 172.3 and 240.2, for example.

III. Claim 18, drawn to a method for screening candidate compounds for binding affinity to the *patched* protein, classified in Class 435, subclass 240.2, for example.

IV. Claim 19, drawn to a method for screening candidate compounds for agonist activity with the *patched* protein.classified in Class 435, subclass 69.1, for example.

V. Claim 20, drawn to a monoclonal antibody specific for a *patched* protein, classified in Class 350, subclass 387.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and V are patentably distinct because the DNA sequence, the expression cassette and the cell of invention I are not limited in use to the preparation of the monoclonal antibody of invention V and can be used for the preparation of nucleic acid probes for hybridizations or recombinant *patched* protein; and the preparation of the monoclonal antibody of invention V does not require the DNA sequence, the expression cassette and the cell of invention I.

Inventions I, II, III and IV are patentably distinct because they are drawn to independent and materially different methods. The method (claim 17) of invention I involves growing a cell comprising an introduced *patched* gene and isolating the expressed *patched* protein, the method of invention II (claim 16) involves integrating a marker gene in embryonic cells, growing the cells and locating the cells during

development, the method of invention III involves combining a candidate compound with a cell and then assaying for binding, and the method of invention IV involves combining a candidate compound with a cell and then assaying for expression of a marker gene.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Bret Field on June 25, 1996, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-12 and 17. Affirmation of this election must be made by applicant in responding to this Office action. Claims 13-16 and 18-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Claims 1-12 and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is suggested that the phrase "A DNA sequence other than present in a chromosome" be replaced with the phrase "A purified and isolated DNA sequence" for clarity. Additionally, the two occurrences of the phrase "*patched* gene" should be replaced with the phrase "*patched* protein" because it is the protein, not the gene, which is encoded by the DNA sequence. Note that claims 2-12 and 17 depend on claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the mannerand

process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 1-12 and 17 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to a purified and isolated DNA sequence encoding a patched protein from animal species which are specifically disclosed, a fragment of said DNA sequence which is specifically taught with regard to making and using, an expression cassette comprising said DNA sequence, a cell comprising said expression cassette, and a method for producing a *patched* protein using said cell.

The first paragraph of 35 U.S.C. 112 requires that the specification be enabling as of the effective filing date of the application for one skilled in the art to make and use the full scope of the invention being claimed. Moreover, the Court in In re Vaeck (20 USPQ 1438, Fed. Cir. 1991) held that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification. In the instant case, the specification is not enabling for a purified and isolated DNA sequence encoding a patched protein from all animal species, all fragments of said DNA sequence of more than 12 bp, an expression cassette comprising said DNA sequences and said fragments, a cell comprising said expression cassette, and a method for producing a *patched* protein using said cell.

With respect to the origin of the isolated *patched* gene sequence, while the claims encompass all animal species, i.e., all insects, all mammals, all birds, all fish, all amphibians, etc., the specification only teaches *patched* gene sequences from a handful of animal species. Moreover, while the claims also encompass all DNA fragments of more than 12 bp, the specification provides little or no guidance on how to make and use all such fragments. Note that claims 7-12 and 17 depend on claim 1 and are directed to an expression cassette, a cell and a method for producing a *patched* protein. However, it is unclear as to how a fragment of only 12 bp is sufficient to produce the *patched* protein. Note also that a 12 bp fragment is very likely to be anticipated by the well known *Drosophila patched* gene sequence. Thus, in view of the unpredictability of the art and the lack of guidance provided in the specification, it would have required undue experimentation for one skilled in the art at the time the claimed invention was made to isolate a DNA sequence encoding a patched protein from all animal species and all fragments thereof of more than 12 bp, and to employ the same in preparing an expression cassette and a cell in order to produce a *patched*

protein. Accordingly, the disclosure is enabling only for claims limited to a purified and isolated DNA sequence encoding a patched protein from animal species which are specifically disclosed, a fragment of said DNA sequence which is specifically taught with regard to making and using, an expression cassette comprising said DNA sequence, a cell comprising said expression cassette, and a method for producing a *patched* protein using said cell.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-6 are rejected under 35 U.S.C. 103 as being unpatentable over either Nakano et al. (A10) or Hooper et al. (A1), when taken with one of Chavrier et al. or Ma et al..

Nakano et al. and Hooper et al. each discloses a DNA sequence encoding a *patched* protein. Each of these teachings differs from the claimed invention in that the encoded *patched* protein is of *Drosophila* origin. However, at the time the claimed invention was made, Chavrier et al. and Ma et al. had each disclosed a

method of cDNA cloning by PCR. Accordingly, it would have been obvious for one of ordinary skill in the art to utilize the *Drosophila patched* gene sequence taught by either Nakano et al. or Hooper et al. in the PCR cloning method taught by one of Chavrier et al. or Ma et al. in order to isolate *patched* gene sequences from other animal species, with a reasonable expectation of success. Thus the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

Claims 7-12 and 17 are rejected under 35 U.S.C. 103 as being unpatentable over either Nakano et al. (A10) or Hooper et al. (A1), when taken with one of Chavrier et al. or Ma et al., as applied to claims 1-6 above, and further in view of Thummel et al..

Thummel et al. teaches expression cassettes, cells transfected with the expression cassettes and a method for producing a protein of interest by growing the transfected cells in culture. Accordingly, the additional modification of the teachings of either Nakano et al. or Hooper et al. by inserting a DNA sequence encoding a *patched* protein other than the *Drosophila patched* protein into an expression cassette and transfecting cells with the expression cassette in order to obtain a recombinant *patched* protein would have been obvious to one of ordinary skill in the art at the time the claimed invention was made. Thus the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication should be directed to Jasemine C. Chambers, Ph. D., at telephone number 703-308-2035.

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